Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470045	08/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arbuckle Memorial Hospital	2011 W Broadway Ave, Sulphur, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The survey was performed on 07/30/18 - 08/01/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant, and the hospital admininistrator at the conclusion of the survey
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written policy and procedure, and interview with the technical consultant, the laboratory failed to follow its written policy and procedure. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed microscopic urinalysis testing and reported the presence of WBC's (White Blood Cells), RBC's (Red Blood Cells), Epithelial Cells, Clue Cells, and bacteria; (2) On the third day of the survey, the surveyor reviewed the laboratory's written policy and procedure for microscopic urinalysis. The policy included instructions for reporting results, as follows: (a) WBC's: Number seen/HPF (per High Power Field) (b) RBC's: Number seen/HPF (c) Epithelial cells: Number seen /HPF (b) Bacteria: 1+ to 4+/HPF (3) The surveyor then reviewed the microscopic urinalysis results for 4 patients and identified the laboratory failed to follow its written policy and procedure for 3 of the 4 patients reports reviewed: (a) Patient #1-Testing performed 02/06/17: (i) Bacteria was reported as "Moderate" (b) Patient #2-Testing performed 12/13/17: (i) Epithelial cells were reported as "Large" (ii) Bacteria was reported as "Large" (c) Patient #3-Testing performed 04/11/18: (i) Epithelial cells were reported as "Rare" (ii) Bacteria was reported as "Large" (4) The surveyor

	reviewed the findings with the technical consultant who stated to the surveyor the laboratory failed to follow its written policy and procedure for reporting microscopic urinalysis results.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure expired testing materials were not used. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed Crossmatch testing (i.e. ABO/Rh typing, Antibody Screen testing, and Compatibility testing) using the tube method; (2) On the second day of the survey, the surveyor reviewed Blood Bank QC (Quality Control) and patient testing records from 21 months (November and December 2016; January through December 2017; and January through July 2018) and identified documentation the laboratory used expired testing materials during 7 of the 21 months reviewed (November and December 2016; January, February, and September 2017; and April and May 2018: (a) Reagent Red Blood Cells A1 (Lot #111098), and Reagent Red Blood Cells B (Lot #113098), which were used for ABO serum blood typing, had a manufacturer's expiration date of 10/21/16 and had been used on 11 days of patient testing: 11/01/16, 11/04/16, 11/16/16, 11/17/16, 11/21/16, 11/22/16, 11/24 /16, 11/25/16, 12/05/16, 12/06/16 and 12/15/16 (b) Reagent Red Blood Cells (Panoscreen) I, II, and III, (Lot #33898), which were used for Antibody Screen testing, had a manufacturer's expiration date of 10/21/16 and had been used on 11 days of patient testing: 11/01/16, 11/04/16, 11/16/16, 11/17/16, 11/21/16, 11/22/16, 11 /24/16, 11/25/16, 12/05/16, 12/06/16 and 12/15/16 (c) Check Cells (IgG coated RBC's) (Lot #33888), which were used for Antiglobulin QC testing, had a manufacturer's expiration date of 10/21/16 and had been used on 11 days of patient testing: 11/01/16, 11/04/16, 11/16/16, 11/17/16, 11/21/16, 11/22/16, 11/24/16, 11/25 /16, 12/05/16, 12/06/16 and 12/15/16 (d) Reagent Red Blood Cells B (Lot #113112) had a manufacturer's expiration date of 01/13/17 and had been used on 9 days of patient testing: 01/14/17, 01/21/17, 01/23/17, 01/24/17, 01/28/17, 01/30/17, 01/31/17, 02/01/17, and 02/04/17 (e) Rh Control, (Lot #33888), used for QC of the Rh antiserum, had a manufacturer's expiration date of 09/08/17, and had been used on 1 day of patient testing: 09/12/17 (f) Reagent Red Blood Cells A1 (Lot #111179) and Reagent Red Blood Cells B (Lot #113098), had a manufacturer's expiration date of 04 /06/18, and had been used on 5 days of patient testing: 04/07/18, 04/11/18, 04/12/18, 04/13/18, and 05/02/18 (g) Check Cells (Lot #05119), used for ABO serum blood typing, had a manufacturer's expiration date of 04/06/18, had been used on 5 days of patient testing: 04/07/18, 04/11/18, 04/12/18, 04/13/18, and 05/02/18 (3) The surveyor reviewed the records with the technical consultant who stated to the surveyor, the documentation on the testing records showed expired reagents had been used, as listed above; (4) Examples of patient Crossmatch testing performed when documentation showed the laboratory used expired materials, follow: (a) Patient #4 - Testing performed on 11/01/16 (b) Patient #5 - Testing performed on 11/16/16 (c) Patient #6 - Testing performed on 11/21/16 (d) Patient #7 - Testing performed on 12/05/16 (e) Patient #8 - Testing performed on 12/31/16 (f) Patient #9 - Testing performed on 01/14

	/17 (g) Patient #10 - Testing performed on 01/28/17 (h) Patient #11 - Testing performed on 01/30/17 (i) Patient #12 - Testing performed on 02/01/17 (j) Patient #13 - Testing performed on 02/04/17 (k) Patient #14 - Testing performed on 09/12/17 (l) Patient #15 - Testing performed on 04/07/18 (m) Patient #16 - Testing performed on 04/13/18 (n) Patient #17 - Testing performed on 05/02/18